K123861

DEC 12 2013

AIDI
BIOMEDICAL, LLC

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8. 510(k) Summary (21 CFR 807.92)

510(k) Owner:	Dr. William Y.S. Hung Chief Executive Officer
Address:	AIDI Biomedical, LLC 34859 Frederick St. #105 Wildomar, CA 92595
Telephone: Fax:	(951) 678-9626 (951) 471-6147
Contact person:	Chen Tian QA Manager (213) 595-9134
Date of Summary Preparation:	November 29, 2012
Name of device:	Dental Implant System
Classification Name:	Endosseous dental implant (21 CFR 872.3640, product code DZE) and Endosseous dental implant abutment (21 CFR 872.3630, product code NHA)
Trade Name:	AIDI Dental Implant System
Classification:	II under 872.3640
Predicate devices(2):	AIDI Dental Implant System (K101755) IDI Implant System (K081806)
Materials:	Implants are made from ASTM F-67 CO Ti Grade 4. Abutments, healing abutments, cover screws, and abutment screws are made from ASTM F-136 Ti6AI4V.

1. Device Description:

The improved AIDI Dental Implant System is a threaded root-form dental implant intended for use in the upper and lower jaw arches to support prosthetic devices, such as an artificial tooth, in order to restore esthetics and chewing function to partially or fully edentulous patients. Also included are straight abutments (which provide cemented and screw retained restorative options), cover screws, abutment screws, and healing abutments.

The AIDI Dental Implant System (current submission) is an improved version of the previously approved AIDI Dental Implant System (K101755). However, the improved AIDI has the same scientific concepts as the predicates IDI Implant System (K081806) and the previous AIDI Dental Implant System (K101755). For instance, they all have the same internal thread in the apical end, the same thread design on external surfaces, and the same surface treatment – Soluble Blast Media (SBM). The subject device and the predicates are all machined from ASTM F-136 Titanium Ti6AL4V ELI. The abutment screws, cover screws, straight abutments, and healing abutments are also machined from the same alloy.

The physical and performance characteristics of the subject device and the predicate devices include a tapered implant body. AIDI dental implants (current submission) have an octagonal interlocking implant/abutment interface. The improved AIDI also has a similar tapered coronal design as the previous AIDI Dental Implant System (K101755).

2. Indication for Use

The newly improved AIDI Dental Implant System (AIDI Fixtures and AIDI Abutments with Screws) is made up of endosseous implants intended to be surgically placed in the bone of the upper or lower jaws to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Straight abutments indicated for both screw retained and cemented restorations are included. The implants are indicated for single or multiple unit restorations and can be used in splinted and non-splinted applications. The device is intended for immediate loading when good primary stability has been achieved with the appropriate occlusal loading.

3. Technical Characteristics

	Subject Device	Predicate Devices	
Name	AIDI Dental Implant System **(Current Submission)** (AIDI Internal Fixture and Abutments)	AIDI Dental Implant System **(Previous)** (AIDI Internal Fixture and Abutments) **K101755**	IDI Implant Systems (IDI Internal Fixtures and Abutments) **K081806**
Material	Titanium ASTM F67 Grade 4 or ASTM F-136 6AL4V ELI	Titanium ASTM F67 Grade 4 or ASTM F-136 6AL4V ELI	Titanium ASTM F67 Grade 4 or ASTM F-136 6AL4V ELI
Coronal Design	Tapered Coronal Design	Tapered Coronal Design	No

Internal Screw Thread	Yes	Yes	Yes
Implant Body Design	Tapered	Tapered	Tapered
Implant Body Diameter (mm)	3.3, 3.7	3.2, 3.7, 4.7, 5.4	3.7, 4.7, 5.4, 6.4
Length (mm)	8.8~16.0	8.8~16.0	8.8~16.0
One-Stage Surgical Procedures	Yes	Yes	No
Two-Stages Surgical Procedures	Yes	Yes	Yes
Implant/ Abutment Interface	Octagonal Interlocking	Hexagonal Interlocking	Hex-Lobe Interlocking
Surface Treatment	Soluble Blast Media (Tricalcium Phosphate/ Hydroxyapatite, conform to ASTM F1185-03)	Soluble Blast Media (Tricalcium Phosphate/ Hydroxyapatite, conform to ASTM F1185-03)	Resorbable media Blasting (Tricalcium Phosphate/ Hydroxyapatite, conform to ASTM F1185-03)
Gamma Sterilized	Yes	Yes	Yes
Attachments	Screw-retained restoration system	Screw-retained restoration system	Screw-retained restoration system

4. Nonclinical Test Summary

The nonclinical test data of the currently submitted AIDI Dental Implant System Torque Test Report revealed high torque strength for AIDI Dental Implants. The predicates IDI (K081806) implants and previous AIDI implants (K101755) resembled the same torque strength.

5. Clinical Test Summary

No clinical studies were submitted.

6. Conclusion

We conclude that our AIDI Dental Implant System (current submission) is substantially equivalent for its intended use and performs as well as the predicates IDI Implant System (K081806) and AIDI Dental Implant System (K101755):

A. The torque strength test data revealed high torque strength for AIDI Dental Implants (current submission). The predicate IDI implant system (K081806) and predicate AIDI Dental Implant System (K101755) resembled the same torque strength.

B. The newly improved AIDI dental implant system is substantially equivalent in terms of materials, design, and technical characteristics to the IDI Implant System (K081806) and AIDI Dental Implant System (previous) (K101755)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 12, 2013

AIDI Biomedical, LLC
Chen Tian
Quality Assurance Manager
34859 Frederick Street, #105
Wildomar, CA 92595

Re: K123861
Trade/Device Name: AIDI Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: November 15, 2013
Received: December 2, 2013

Dear Mr. Tian:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID

FOR

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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7. Indications for Use

Device Name: **AIDI Dental Implant System**

Indications for Use:

The newly improved AIDI Dental Implant System (AIDI Fixtures and AIDI Abutments with Screws) is made up of endosseous implants intended to be surgically placed in the bone of the upper or lower jaws to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Straight abutments indicated for both screw retained and cemented restorations are included. The implants are indicated for single or multiple unit restorations and can be used in splinted and non-splinted applications. The device is intended for immediate loading when good primary stability has been achieved with the appropriate occlusal loading.

Prescription use: ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use: ____ (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner DDS, MA

Mary S. Runner -S
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